

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/807,541	AKIMOTO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dr. Kailash C. Srivastava	1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 07/05/2006.
2. ☒ The allowed claim(s) is/are 81-97.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                    |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>07/07/2006</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                           |
|   | 9. <input type="checkbox"/> Other _____.   |

## Examiner's Proposed Amendment

### DRAFT

#### In the Claims:

Claims 1-80 are cancelled. Following is the list of new Claims.

Claim 81 (New): An isolated biologically homogeneous microorganism that secretes a lipid vesicle extracellularly, wherein said lipid vesicle encapsulates a lipid, said lipid is comprised of unsaturated fatty acid, wherein said microorganism is a strain selected from the group consisting of *Mortierella alpina* SAM 2241 and *Mortierella alpina* SAM 2242.

Claim 82 (New): The microorganism of claim 81, wherein said unsaturated fatty acids are fatty acids having 18 or more carbons and two or more double bonds.

Claim 83 (new): The microorganism of claim 81, which when grown on a solid medium forms around its colony lipid vesicles that contain lipid, and/or said microorganism when cultured in a transparent liquid culture medium makes the culture liquid cloudy.

Claim 84 (new): The microorganism of claim 81, wherein 50% or more of said extracellularly secreted lipid is comprised of triglyceride.

Claim 85 (new): The microorganism of claim 81, wherein said unsaturated fatty acid is arachidonic acid.

Claim 86 (new): The microorganism of claim 85, wherein said lipid comprises 10% or more arachidonic acid relative to the total fatty acids.

Claim 87 (new): The microorganism of claim 82, wherein said unsaturated fatty acid is arachidonic acid.

Claim 88 (new): A method to produce lipid vesicles comprising culturing the microorganism of claim 81 in a liquid culture medium and collecting the lipid vesicles from the liquid culture medium.

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### Examiner's Amendment/Comments

1. Applicants' Statement filed 05 July 2006 describing the substance of Interview on 07 June 2006 subsequent to an Advisory action mailed 21 March 2006 is acknowledged and entered.
2. The Interview Summary from the Interview on 07 June 2006 was mailed on 27 June 2006.

### CLAIMS STATUS

3. Claims 1-80 are cancelled.
4. Claims 81-97 are added.
5. Claims 81-97 are pending and are examined on merits.

### Examiner's Amendment

6. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 CFR §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on 07 July 2006 and confirmed on 27 July 2006 with Ms. Mercedes K. Meyers from Applicants' Representative's Office.

#### In the Claims:

Claims 1-80 are cancelled. Following is the list of new Claims.

Claim 81 (New): An isolated biologically homogeneous microorganism that secretes a lipid vesicle extracellularly, wherein said lipid vesicle encapsulates a lipid, said lipid is comprised of unsaturated fatty acid, wherein said microorganism is a strain selected from the group consisting of *Mortierella alpina* SAM 2241 and *Mortierella alpina* SAM 2242.

Claim 82 (New): The microorganism of claim 81, wherein said unsaturated fatty acids are fatty acids having 18 or more carbons and two or more double bonds.

Claim 83 (new): The microorganism of claim 81, which when grown on a solid medium forms around its colony lipid vesicles that contain lipid, and/or said

microorganism when cultured in a transparent liquid culture medium makes the culture liquid cloudy.

Claim 84 (new): The microorganism of claim 81, wherein 50% or more of said extracellularly secreted lipid is comprised of triglyceride.

Claim 85 (new): The microorganism of claim 81, wherein said unsaturated fatty acid is arachidonic acid.

Claim 86 (new): The microorganism of claim 85, wherein said lipid comprises 10% or more arachidonic acid relative to the total fatty acids.

Claim 87 (new): The microorganism of claim 82, wherein said unsaturated fatty acid is arachidonic acid.

Claim 88 (new): A method to produce lipid vesicles comprising culturing the microorganism of claim 81 in a liquid culture medium and collecting the lipid vesicles from the liquid culture medium.

Claim 89 (new): The method of claim 87, wherein said culturing and said collecting are continuous.

Claim 90 (new): A method to produce a lipid, comprising culturing the microorganism of claim 81 in a liquid culture medium, collecting the lipid vesicles from the liquid culture medium, wherein said lipid vesicles encapsulate said lipid, and separating said lipid from said lipid vesicles, wherein said lipid contains fatty acids.

Claim 91 (new): The method of claim 89, further comprising isolating unsaturated fatty acids from said lipid.

Claim 92 (new): An isolated biologically homogeneous microorganism, wherein said microorganism is *Mortierella alpina* SAM 2241, or *Mortierella alpina* SAM 2242 having a property of extracellularly secreting a lipid as lipid vesicles encapsulating said lipid, wherein said lipid is comprised of unsaturated fatty acids that have 18 carbons and three or more double bonds, or 20 or more carbons and two or more double bonds.

Claim 93 (new): The microorganism of claim 91, wherein said microorganism when grown on a solid medium forms lipid-containing lipid vesicles around the colonies

Claim 89 (new): The method of claim 87, wherein said culturing and said collecting are continuous.

Claim 90 (new): A method to produce a lipid, comprising culturing the microorganism of claim 81 in a liquid culture medium, collecting the lipid vesicles from the liquid culture medium, wherein said lipid vesicles encapsulate said lipid, and separating said lipid from said lipid vesicles, wherein said lipid contains fatty acids.

Claim 91 (new): The method of claim 89, further comprising isolating unsaturated fatty acids from said lipid.

Claim 92 (new): An isolated biologically homogeneous microorganism, wherein said microorganism is *Mortierella alpina* SAM 2241, or *Mortierella alpina* SAM 2242 having a property of extracellularly secreting a lipid as lipid vesicles encapsulating said lipid, wherein said lipid is comprised of unsaturated fatty acids that have 18 carbons and three or more double bonds, or 20 or more carbons and two or more double bonds.

Claim 93 (new): The microorganism of claim 91, wherein said microorganism when grown on a solid medium forms lipid-containing lipid vesicles around the colonies thereof, and/or when cultured in a transparent liquid culture medium makes said liquid culture medium cloudy.

Claim 94 (new): The microorganism of claim 91, wherein said extracellularly secreted lipid comprises 50% or more triglyceride.

Claim 95 (new): The microorganism of claim 91, wherein said unsaturated fatty acid is selected from the group consisting of  $\gamma$ -linolenic acid; arachidonic acid; 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) and  $\omega$ -9 highly unsaturated fatty acids.

Claim 96 (new): A method to produce a lipid comprised of unsaturated fatty acids, which method comprises culturing the microorganism of claim 91 in a liquid culture medium and collecting the lipid from said liquid culture medium.

Claim 97 (new): The method of claim 94, wherein said culturing and said collecting is continuous.

thereof, and/or when cultured in a transparent liquid culture medium makes said liquid culture medium cloudy.

Claim 94 (new): The microorganism of claim 91, wherein said extracellularly secreted lipid comprises 50% or more triglyceride.

Claim 95 (new): The microorganism of claim 91, wherein said unsaturated fatty acid is selected from the group consisting of  $\gamma$ -linolenic acid; arachidonic acid; 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) and  $\omega$ -9 highly unsaturated fatty acids.

Claim 96 (new): A method to produce a lipid comprised of unsaturated fatty acids, which method comprises culturing the microorganism of claim 91 in a liquid culture medium and collecting the lipid from said liquid culture medium.

Claim 97 (new): The method of claim 94, wherein said culturing and said collecting is continuous.

### Examiner's Reasons For Allowance

7. The following is Examiner's statement of reasons for allowance:

The closest prior art is: Shinmen et al. (EP Application 0 276 982 A2).

The composition or method disclosed in the cited prior art reference does not teach a microorganism or fungus that produces extracellular lipid as lipid vesicles on the periphery of the growing colony of said microorganism, when said microorganism is cultured on a solid medium, nor does it make the liquid culture medium "cloudy" when said isolated biologically homogeneous colony is transferred and grown into said liquid medium. Thus, the prior art reference cited *supra* does not teach or reasonably suggest a method or a composition that is the subject matter of the claimed invention.


Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 81-97 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday, 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

 Kailash C. Srivastava, Ph.D.  
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August 1, 2006



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